DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 7, 2014

Gemss Medical Systems Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K133695
Trade/Device Name: TITAN 11
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 15, 2014
Received: July 22, 2014

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133695

Device Name
Stationary X-ray System / TITAN 11

Indications for Use *(Describe)*

TITAN 11 is a diagnostic x-ray system for generation of x-rays for examination of various anatomical regions. This device is not intended for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 07

510(k) SUMMARY

510(k) SUMMARY
For TITAN 11

Submitted by:

GEMSS MEDICAL SYSTEMS CO., LTD.
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Contact – Mr. Sangwoo Lee
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This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date: July, 17th, 2014

1. General Information:

Establishment:
GEMSS MEDICAL SYSTEMS CO., LTD.
61, dunchon-daero 541 beon-gil jungwon-gu seongnam-si,
KOREA, REPUBLIC OF 468-865
Registration Number: 3003384390

GMESS MEDICAL SYSTEMS CO., LTD. is the holder/owner for this 510(k).

US Agent:
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2. Official Correspondent Contact:

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3. Device name and Classification

Trade Name : TITAN 11
Classification Name Stationary X-ray System
Classification Panel : Radiology
Classification Regulation : 21 CFR 892. 1680
Device Classification : Class Ⅱ
Product Code : KPR

4. Legally Marketed Predicated Device

Trade Name : KODAK DIRECTVIEW DR 7500 SYSTEM, MODEL 8791345
510(k) Clearance # : K051258
Clearance date : 06/01/2005
Classification Name : Stationary X-ray System
Classification Panel : Radiology
CFR Section : 21CFR 892.1680
Device Class : Class Ⅱ
Product Code : KPR

5. Device Description

TITAN 11, the high frequency inverter type of Radiographic system is operated by the built-in operation program. TITAN 11 digital X-ray imaging system is to be used to take and store image for diagnosis of patients. It consists of the SSXI detector, X-ray Generator, X-ray tube, X-ray Collimator, PC, Detector Stand, Tube Stand, Mobile Table, PU-30(Power Supply) and viewing software. Optional devices include AEC, DAP, Hand or Foot Exposure Switch.

6. Indications for Use

The TITAN 11 is a diagnostic x-ray system for generation of x-rays for examination of various anatomical regions. This device is not intended for mammography.

7. Substantial Equivalence

TITAN 11 and components are conforms to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, clinical-, and risk management, it is confirmed that TITAN 11 is substantially equivalent to the predicate device.

ITEM	Contents	GEMSS MEDICAL (Model TITAN 11)	Predicate device (K051258)	SE-#
Indications for use		The TITAN 11 is a diagnostic x-ray system for generation of x-rays for examination of various anatomical regions. This device is	The KODAK DirectView DR 7500 system is a permanently installed diagnostic X-ray system for generation of X-ray for examination of various	same

		not intended for mammography.	anatomical regions.	
Software	Name	X-view 4	KODAK direct view EVP software	SE-1
DICOM compatibility	DICOM 3.0	DICOM 3.0 compliance	DICOM 3.0 compliance	Same
TFT Detector	Detector type	CsI	CsI	Same
	Pixels	3008 (v) x 3072 (v)	3000 x 3000	SE-2
	Output data	16 bit gray scales tiff	16,384 capture; 4,096 gray levels output	
	Spatial resolution (DIGITAL SYSTEM)	3.4 lp/mm	3.5 lp/mm	
	Application	DR-Digital radiography	DR-Digital radiography	same
X-ray Generator	Description	40kW	80kW	SE-3
	AEC	Yes	Yes	same
X-ray Tube	Anode Heat Content (Heating Unit)	140kHU	400kHU	SE-4
PC	General purpose PC	YES	YES	same
Detector STAND	U-D movements (At center)	350~1,800mm(1450mm, 40mm/sec) : 1400mm more than.	47 (18.5) table; 152.4 (60) wall	SE-5
Mobile Table	Table top dimensions (L x W)	2000X700mm	2200X868mm	
	Table lock	wheel lock	Mechanical lock	
	Maximum patient weight	300kg	342kg	

8. Difference Discussion

SE-#	SE discussion
SE-1	TITAN 11 software (X-view 4.1) receives patient information from work-list, and corrects images, and transfers the information to PACS same as the predicate device. A series of process for communication is same as well. TITAN 11 software has all functions that predicate device has, including patient information editing, input value adjustment (ex. kVp, mA, mAs, Time), and image correction such as W/L, Marking, Crops and so on. Therefore the software programs used in the new and predicated device are substantially equivalent.
SE-2	Image pixels size and spatial resolution are similar with the predicate device. The differences are not significant in terms of the overall quality of patient image acquisition. TITAN 11 has more number of pixels than the predicate. The performance specification, specifically spatial resolution, of Titan 11 is better than the predicate, and this does not raise any new concern for safety and effectiveness.

SE-3	The generation capacity of proposed device is lower than the predicate device. Even though the capacity is lower, the conclusion of the radiologist's review demonstrates compatible image quality using short/long scale contrast control processing method. While the X-ray generation capacity is lower than the predicate device, the exposure time for the subject device may be set longer than predicate device for compatible image quality compared to the predicate device.
SE-4	The anode heating unit of the subject device is lower than the predicate device. This issue is related to the overheating problem. The proposed device is able to shoot successively240 times per minute without over heating which is lower than that of predicate device. However, it is deemed sufficient and acceptable within the hospital / clinic operating parameter. Therefore this does not raise new safety.
SE-5	The predicate device table is available for "Ceiling, Wall Stand, up/down", TITAN 11 is composed of tube stand, detector stand, mobile table. TITAN 11 has less restriction than the predicate in terms of spacing. Both TITAN 11 and the predicate provide various patient positions for radiographic exposure, such as standing, lying, and sitting.

9. Summary of the technological characteristics of the device compared to the predicate device:

The indications for use, mechanical components, performances and safety characteristics of Titan 11 described in this 510(k) are similar to those of the predicate device.

The primary differences are the specifications of X-ray tube, and X-ray generator of the subject device. The pixel matrix for the subject device is higher than that of the predicate device while the X-ray generator and X-ray tube anode heat content (Heating Unit) for the new device are smaller than those of the predicate device. However, as demonstrated by the conclusion of the clinical image review by an expert, both devices are capable of generating quality radiographs sufficient for patient diagnosis.

The image quality of radiographs depends on various factors including the pixel size of the detector, kVp, mA and X-ray exposure time. As demonstrated in the clinical image review report, the technological characteristics of the subject device as well as its superior pixel matrix are more than adequate to obtain radiographs with compatible image quality compared to the predicate device.

These differences do not have an effect on safety and effectiveness compared to the predicate device.

10. Performance Testing/Data

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence. Safety compliance checking (including EMC, and so on) was evaluated according to the IEC Standards. GMESS MEDICAL SYSTEMS Co., Ltd certifies conformance to Voluntary Standards covering electrical and Mechanical safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness.

10.1 Description of non-clinical tests.

The proposed device(TITAN11) has undergone electrical safety and electromagnetic compatibility testing, as well as software validation and risk analysis.

Compliance evidences were submitted for the following standards:

- IEC 60601-1: Test Report issued by 3rd party testing lab

- IEC 60601-1-2: Test Report issued by 3rd party testing lab
- IEC 60601-1-3: Test Report issued by 3rd party testing lab
- IEC 60601-2-54: Test Report issued by 3rd party testing lab
- IEC 62304: Software development DHF package by GEMSS MEDICAL SYSTEMS. Co., Ltd.
- EPRC Standard: 21 CFR 1020.30 and 31: In-house Test Report issued by GEMSS MEDICAL SYSTEMS. Co., Ltd.
- ISO 14971: Risk management file by GEMSS MEDICAL SYSTEMS. Co., Ltd.

10.2 Description of clinical tests.

Clinical images from both the subject and the predicate devices were obtained in accordance with the FDA Guidance Document on Solid State Imaging Devices and the clinical images were evaluated by a radiologist with credentials equivalent to a US board certification. The evaluation of the qualified radiologist in the study shows that TITAN 11 provides images of equivalent diagnostic capability to the predicate device. It demonstrates that TITAN 11 is substantially equivalent with the predicate device.

11. Conclusion as to Substantial Equivalence

TITAN11 is substantially equivalent to the predicate device KODAK DIRECTVIEW DR 7500 SYSTEM (K051258). These 2 devices are same or very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, their appearance, the user interfaces and the capacity of X-ray generator and X-ray tube are different. However the compliance reports, performance demonstrations and description of clinical review result in this submission STED provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, GEMSS MEDICAL SYSTEMS CO., LTD. concludes TITAN 11 is substantially equivalent with the predicate device KODAK DIRECTVIEW DR 7500 SYSTEM (K051258).